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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,392	10/21/2001	Rupert Austin	3525-28	7217

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/403,392

Applicant(s)

AUSTIN ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-17 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) *filed on*
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1-5-00*
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

This is a 371 of PCT/SE 99/01333 filed on 08-03-99. The preliminary amendment of 10-21-01 has been entered. The amendment only changes the dependency of claims 3-16. No new matter is noted. Claims 1-17 are pending.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 8-10, and 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following rejections apply:

a. Claims 8-10 are improper dependent claims because they fail to further limit claim 7. Said claims recite intermediates which are compounds, while claim 7 is a process claim. Furthermore, the claims need to be completed with either chemical structures or chemical names.

b. Claim 12 recites the phrase "as claimed in as defined above" which is rhetorically awkward, and unclear as to which claims said phrase refers to. In other words, it is unclear if claim 12 refers to just claim 11 or all the above claims including claim 11.

Art Unit: 1624

c. Claim 13 appears as a substantial duplicate of claim 1 because the preamble "for use in therapy" does not contribute to a structural change, and therefore, does not have patentable weight.

2. **Use Claims:** Claims 13 and 14 provide for the use of a compound of formula (I), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13 and 14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Scope of Enablement:** Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the preparation of compounds of formula I, does not reasonably provide enablement for the use of said compounds. The specification does

not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The quantity of experimentation necessary;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The breadth of the claims;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

4. The specification only discloses the procedures for bio-assay methods, but does not indicate which compound has activity, and which does not. It does not indicate that all compounds have activity. Thus, for the broad scope of compounds claimed herein, the skilled chemist would have to carry out undue experimentation to find out which one has activity as CXCR2 receptor antagonist. Furthermore, the specification does not reveal a dosage that can be administered to a patient. Page 32 simply describes the pharmaceutical composition comprising 0.05-99% w of active ingredient. A percentage of 99% w of active ingredient is unrealistic -- one virtually administers the claimed compound without any pharmaceutical carrier. Even the preferred 50% w of active ingredient is not meaningful. In standard pharmaceutical practice, the

dosage is given in mg/kg/d, which is not disclosed. Furthermore, the therapeutic index of the compounds of formula (I) is not known. Thus, undue experimentation is inevitable for the skilled clinician to administer a compound of formula (I) to a patient.

5. **Enablement:** Claims 11-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The pharmaceutical composition described on page 32 does not allow the skilled chemist to make a formulation that can be administered to a patient. As discussed in the above paragraph, one cannot treat any disease without a proper dosage. In the instant case, not only one does not know which compound has activity, one cannot make a pharmaceutical composition that can be administered in a safe manner. Thus, it follows that one must carry out undue experimentation to treat psoriasis as well as other diseases that are related to chemokine.

#### ***Claim Objections***

6. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1624

***Information Disclosure Statement***

7. The IDS of 1-5-00 has been considered. It is noted that the compound disclosed in J. Amer. Chem. Soc., Vol. 73 has been excluded from claim 1.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-5:00) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



***Tamthom N. Truong***  
***Examiner***  
***Art Unit 1624***

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May 14, 2003